



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0755; FRL-9402-8]

Dinotefuran; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation modifies existing time-limited tolerances established at 40 CFR 180.603 under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), for residues of dinotefuran in or on pome fruit and stone fruit by raising them from 1.0 ppm to 2.0 ppm. A document published in the **Federal Register** of November 9, 2012, which first established the tolerances in response to EPA's granting of an emergency exemption under Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on pome fruit and stone fruit. The previous tolerances were supported by surrogate residue data in pears. Additional residue data has been produced on peach indicating that residues may be higher than suggested by the residue data in pears. Review of the new data has concluded that the tolerance levels for pome and stone fruits should be increased to 2.0 ppm. Therefore, this regulation modifies the maximum permissible level for residues of dinotefuran in or on these commodities by raising them from 1.0 ppm to 2.0 ppm. The time-limited tolerances expire on December 31, 2015.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date* **60** days

*after date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the*

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0755, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703)305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0755 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the Federal Register*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any

Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0755, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is modifying the time-limited tolerances for residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine including its degradates DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea in or on Fruit, stone, Group 11, and Fruit, pome, Group 12 by revising to 2.0 parts per million (ppm). The current time-limited tolerances were first established for these crop groups at 1.0

ppm in a rule published in the **Federal Register** document on November 9, 2012. These modified time-limited tolerances expire on December 31, 2015.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established or modified without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish or modify a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Dinotefuran on Pome and Stone Fruit and FFDCA Tolerances

Eight state lead agricultural agencies have requested and received emergency exemptions for the use of dinotefuran on pome and stone fruits to control the brown marmorated stink bug (BMSB) for the past two years. The states are: Delaware, Maryland, Michigan, New Jersey North Carolina, Pennsylvania, Virginia, and West Virginia. The States claimed that the abrupt increase and spread of damaging populations of BMSB, a recently introduced invasive species, resulted in an urgent and non-routine situation with significant economic losses of over 20% expected without the use of dinotefuran as an additional pest management tool.

After having reviewed the submissions, EPA determined that emergency conditions exist for these States, and that the criteria for approval of emergency exemptions are met. EPA has authorized specific exemptions under FIFRA section 18 for the use of dinotefuran on pome fruit and stone fruit for control of the BMSB in the eight states listed previously. Time-limited tolerances were established at 1.0 ppm in or on stone and pome fruits, previously, in connection with these actions. The tolerances were supported by surrogate residue data in pears. Since then, additional residue data has been produced in peach indicating that residues may be higher than suggested by the pear data. EPA has reviewed the new data and concluded that a tolerance level of 2.0 ppm is appropriate.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by raising the tolerances for residues of dinotefuran in or on pome fruit and stone fruit. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18.

Consistent with the need to move quickly on the emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this modification of the initial tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2015, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on pome fruit and stone fruit after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances were approved under emergency conditions, EPA has not made any decisions about whether dinotefuran meets FIFRA's registration requirements for use on pome fruit and stone fruit or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of dinotefuran by a State for special local needs under FIFRA section 24(c). Nor do these

tolerances by themselves serve as the authority for persons in any State other than those named previously in this notice to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for dinotefuran, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption use and the time-limited tolerances for residues of dinotefuran on pome fruit and stone fruit at 2.0 ppm. EPA's assessment of exposures and risks associated with these time-limited tolerances follows.

A. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in

conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for dinotefuran used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of September 12, 2012 (77 FR 56133) (FRL-9359-6). These endpoints remain unchanged since that date.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dinotefuran, EPA considered exposure under the time-limited tolerances as modified by this action as well as all existing dinotefuran tolerances in 40 CFR 180.603. EPA assessed dietary exposures from dinotefuran in food as follows:

i. *Acute and Chronic exposures.* Acute and chronic effects were identified for dinotefuran. In estimating acute and chronic dietary exposures, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance level residues for all commodities.

ii. *Cancer.* Based on the data referenced in Unit IV.A., EPA has concluded that dinotefuran does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iii. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for dinotefuran. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dinotefuran in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dinotefuran. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST), Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and the Screening Concentration in Ground Water (SCI-GROW) models the estimated drinking water concentrations (EDWCs) of dinotefuran for acute exposures are estimated to be 269 parts per billion (ppb) for surface water and 4.9 ppb for ground water; and for chronic exposures for non-cancer assessments are estimated to be 253-257 ppb for surface water and 4.9 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure models. For acute dietary risk assessment, the water concentration value of 269 ppb was used to assess the dietary exposure contribution from drinking

water. For chronic dietary risk assessment, the water concentration value of 257 ppb was used to assess the dietary exposure contribution from drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Dinotefuran is currently registered for the following uses that could result in residential exposures: Turf, ornamentals, vegetable gardens, pets, indoor aerosol sprays, and crack and crevice sprays. EPA assessed residential exposure using the following assumptions: Residential handler exposures were not assessed because no dermal or inhalation hazards were identified. For this same reason, postapplication residential dermal and inhalation exposure scenarios were not assessed. The Agency only considered post-application scenarios in which incidental oral exposures to children are expected. The oral exposures assessed included incidental oral exposures from turf, ant bait, ready to use garden trigger sprayers, dog and cat spot-on treatment, indoor broadcast, and indoor crack and crevice uses. Of all these scenarios, treated turf was determined to result in the highest levels of exposure. In assessing risks from residential exposures, EPA combines different residential sources of exposure that could reasonably be expected to occur on the same day. While it is possible for children to be exposed to indoor broadcast sprays on hard surfaces/carpets and to spot-on treatment to cats or dogs on the same day, these exposures have not been combined in this assessment because incidental oral hand-to-mouth exposure from treated turf is higher and still results in an MOE that does not exceed the Agency’s Level of Concern (LOC). Further information regarding EPA standard

assumptions and generic inputs for residential exposures may be found at:

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found dinotefuran to share a common mechanism of toxicity with any other substances, and dinotefuran does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dinotefuran does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

C. *Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the pre-natal studies, no maternal or developmental toxicity was seen at the limit dose in rats. In rabbits, maternal toxicity manifested as clinical signs of neurotoxicity but no developmental toxicity was seen. In the reproduction study, parental and offspring toxicity was seen at the limit dose. Parental toxicity included decreased body weight gain, transient decrease in food consumption, and decreased thyroid weights. Offspring toxicity was characterized as decreased forelimb grip strength or hindlimb grip strength in the F1 pups. There was no adverse effect on reproductive performance at any dose. In the developmental neurotoxicity study, no maternal or offspring toxicity was seen at any dose including the limit dose.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for dinotefuran is complete.
- ii. The neurotoxic potential of dinotefuran has been adequately considered.

Dinotefuran is a neonicotinoid and has a neurotoxic mode of pesticidal action. Consistent with the mode of action, changes in motor activity were seen in repeat-dose studies, including the subchronic neurotoxicity study. Additionally, decreased grip strength and brain weight was observed in the offspring of a multi-generation reproduction study albeit at doses close to the limit dose. For these reasons, a developmental neurotoxicity study was required. Upon review of the developmental neurotoxicity study, it was concluded that there is no evidence of a unique sensitivity to the developing nervous

system since no effects on neurobehavioral parameters were seen in the offspring at doses that approached or exceeded the limit dose.

iii. There is no evidence that dinotefuran results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dinotefuran from potential residues in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by dinotefuran.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dinotefuran will occupy 12% of the aPAD for Children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dinotefuran from food and water will utilize 5.7% of the cPAD for Children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in the unit regarding residential use patterns, chronic residential exposure to residues of dinotefuran is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Dinotefuran is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to dinotefuran.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOE of 690 for Children 1-2 years old from hand to mouth exposure from treated turf, the scenario with the highest exposure. Because EPA's level of concern for dinotefuran is when MOEs are less than 100, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term exposure is not expected for the adult residential exposure pathways. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure

estimate. For children, intermediate-term incidental oral exposures could potentially occur from indoor uses. However, while it is possible for children to be exposed for longer durations, the magnitude of residues is expected to be lower due to dissipation or other activities. Since incidental oral short- and intermediate-term toxicity endpoints and points of departure are the same, the short-term aggregate risk estimate, which includes the highest residential exposure estimate (from turf), is protective of any risks from intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, dinotefuran is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to dinotefuran residues. A more detailed discussion of the aggregate risk assessments and determination of safety may be found at <http://www.regulations.gov> in Docket ID number EPA-HQ-OPP-2012-0755, in the aggregate human risk assessment document for this action, entitled “Dinotefuran ID#: 13MI04 Section 18 Emergency Exemption for Use on Pome Fruits and Stone Fruits in Michigan to Control Brown Marmorated Stink Bugs.”

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies (a high performance liquid chromatography/tandem mass spectrometry (HPLC/MS/MS) method for the determination of residues of dinotefuran, and the metabolites DN, and UF; an

HPLC/ultraviolet (UV) detection method for the determination of residues of dinotefuran; and HPLC/MS and HPLC/MS/MS methods for the determination of DN and UF) are available to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established MRLs for dinotefuran in or on pome fruit and stone fruit.

VI. Conclusion

Therefore, the established time-limited tolerances for residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine including its metabolites and degradates, in or on pome fruit and stone fruit are modified by raising them to 2.0 ppm. These tolerances expire on December 31, 2015.

VII. Statutory and Executive Order Reviews

This final rule modifies tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, but not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*)

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 10, 2014.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.603, revise the table in paragraph (b) to read as follows:

§180.603 Dinotefuran; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Fruit, pome, Group 11	2.0	12/31/2015
Fruit, stone, Group 12	2.0	12/31/2015

* * * * *

[FR Doc. 2014-01079 Filed 01/21/2014 at 8:45 am; Publication Date: 01/22/2014]